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|--|---------------------------------------|---------------------------------------|---------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/571,268 | 07/13/2006 | Tomoko Syofuda | Q93176 | 4770 |
| 23373 7590 10/11/2007 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 | | | EXAMINER | |
| | | | WANG, CI | WANG, CHANG YU |
| WASHINGTON, DC 20037 | | | . ART UNIT | PAPER NUMBER |
| | | | 1649 | • |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 10/11/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | |
|--|---|--|--|--|--|
| | 10/571,268 | SYOFUDA ET AL. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | Chang-Yu Wang | 1649 | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | |
| Status | | | | | |
| 1) Responsive to communication(s) filed on 3/9/0 2a) This action is FINAL . 2b) This 3) Since this application is in condition for allowar closed in accordance with the practice under E | action is non-final. nce except for formal matters, pro | | | | |
| Disposition of Claims | | | | | |
| 4) Claim(s) 1-19 is/are pending in the application. 4a) Of the above claim(s) is/are withdray 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-19 are subject to restriction and/or expressions. | vn from consideration. | | | | |
| Application Papers | | | | | |
| 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other: | ate | | | |

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I; claim(s) 1, drawn to a DNA comprising SEQ ID NO:1.

Group II, claim(s) 2 (in part), drawn to a DNA comprising SEQ ID NO:2.

Group III, claim(s) 2 (in part), drawn to a DNA comprising SEQ ID NO:3.

Group IV, claim(s) 3, drawn to a peptide comprising SEQ ID NO:4.

Group V, claim(s) 4, drawn to a peptide comprising SEQ ID NO:5.

Group VI, claim(s) 5, drawn to a peptide comprising SEQ ID NO:6.

Group VII, claim(s) 6-8, drawn to an antibody against SEQ ID NO:4.

Group VIII, claim(s) 9, drawn to a method for detecting nerve stem/progenitor cells using SEQ ID NO:1.

Group IX, claim(s) 10, drawn to a method for a drug for nerve differentiation factor or inhibitor of nerve differentiation.

Group X, claim(s) 11, drawn to an antibody against SEQ ID NO:5.

Group XI, claim(s) 12, drawn to an antibody against SEQ ID NO:6.

Group XII, claim(s) 13 (in part), drawn to a method for detecting nerve stem/progenitor cells using SEQ ID NO:2.

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Group XIII, claim(s) 13 (in part), drawn to a method for detecting nerve stem/progenitor cells using SEQ ID NO:3.

- Group XIV, claim(s) 14, drawn to a method for detecting nerve stem/progenitor cells using SEQ ID NO:4.
- Group XV, claim(s) 15, drawn to a method for detecting nerve stem/progenitor cells using SEQ ID NO:5.
- Group XVI, claim(s) 16, drawn to a method for detecting nerve stem/progenitor cells using SEQ ID NO:6.
- Group XVII, claim(s) 17, drawn to a method for detecting nerve stem/progenitor cells using an antibody against SEQ ID NO:4.
- Group XVIII, claim(s) 18, drawn to a method for detecting nerve stem/progenitor cells using an antibody against SEQ ID NO:5.
- Group XIX, claim(s) 19, drawn to a method for detecting nerve stem/progenitor cells using an antibody against SEQ ID NO:6.
- 2. The inventions listed as Groups I-XIX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:
- 3. The 1st claimed invention is drawn to a DNA comprising SEQ ID NO:1, which is anticipated by prior art references. Niwa et al. (WO2003078631, published Sep 25, 2003, as in IDS) disclosed an DNA of SEQ ID NO:4 having 100% identity to the instant SEQ ID NO:1, which meets the limitation of the 1st claim. Loring et al. (US6682888, issued on Jan 27, 2004, priority May 5, 2000) teaches a DNA of SEQ ID NO: 65 having

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99.9% identity to the instant SEQ ID NO:1, which meets the limitation of a part of the base sequence of SEQ ID NO:1. In addition, as also found in the International Search Report, the Invention of the Group I was found to have no special technical feature that defined the contribution over the prior art of Cumienny et al. (Cell 2001, 107: 27-41, as in IDS). Cumienny et al. teach DNA of instant SEQ ID NO:1 and the protein encoded by SEQ ID NO:1 (see p.32; p.40), which meet the limitation of claim 1. Therefore, claim 1 is anticipated by Niwa et al. (WO2003078631), US6682888 and Cumienny et al.

The sequence search results disclose as follows:

SEQ ID NO:1

```
ADG14343
    ADG14343 standard: DNA: 2109 BP.
    ADG14343;
    26-FEB-2004
DT
                 (first entry)
    Human NC1 coding sequence
    Human; NC1; NC2; NC3; PHHI; pancreas beta-cell; insulin; antidiabetic;
    neuroprotective; gene; ds.
os
    Homo sapiens.
    Key
FH
                    Location/Qualifiers
FT
    CDS
                    174. .917
FT
                     /*tag= a
                     /product= "Human NC1"
FT
ΡN
    WO2003078631-A1
PD
    25-SEP-2003.
    06-MAR-2003; 2003WO-JP002620.
PR
    15-MAR-2002; 2002JP-00071592.
     (KANF ) KANEKA CORP.
ΡI
    Niwa H,
            Yamashita K;
DR
    WPI; 2003-767524/72.
    P-PSDB; ADG14340.
    Familial persistent hyperinsulinemic hypoglycemia of infancy (PHHI)
    patient-expressed genes for detecting and screening e.g. proliferative
    insulin-producing cells in treatment of PHHI.
     Claim 4; SEQ ID NO 4; 34pp; Japanese.
    The present invention relates to human NC1, NC2 and NC3 proteins and
    coding sequences (ADG14340-ADG14345). The coding sequences are useful for
    detecting and screening proliferative insulin-producing cells as well as
    differentiation and proliferation of such cells and their precursors as
    analogous cells in treatment of e.g. PHHI and diseases due to
     differentiation/proliferation abnormality, diseases of the nervous system
    and pancreas. The coding sequences are also useful as spontaneous
    proliferation models of pancreas beta-cells. The novel genes NC1, NC2 and
    NC3 were isolated from the pancreas of PHHI patients, which were used in
    testing for the detection of proliferative insulin-producing cells or
    pancreas beta-cells by Northern analysis.
     Sequence 2109 BP; 548 A; 577 C; 459 G; 525 T; 0 U; 0 Other;
                         100.0%; Score 749; DB 10; Length 2109;
                         100.0%; Pred. No. 3.5e-206;
  Best Local Similarity
          749; Conservative
                                0; Mismatches
            1 GGAGCTTGGTAATGCAGGTGGTGAAGGAGCAGGTTATGAGAGCACTTACAACCAAGCCTA 60
Qv
              163 GGAGCTTGGTAATGCAGGTGGTGAAGGAGCAGGTTATGAGAGCACTTACAACCAAGCCTA 222
           61 GCTCCCTGGACCAGTTCAAGAGCAAACTGCAGAACCTGAGCTACACTGAGATCCTGAAAA 120
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Db
        223 GCTCCCTGGACCAGTTCAAGAGCAAACTGCAGAACCTGAGCTACACTGAGATCCTGAAAA 282
        Oν
           TCCGCCAGTCCGAGAGGATGAACCAGGAAGATTTCCAGTCCCGCCGATTTTGGAACTAA 342
Db
        181 AGGAGAAGATTCAGCCAGAAATCTTAGAGCTGATCAAACAGCAACGCCTGAACCGCCTTG 240
           Db
        343 AGGAGAAGATTCAGCCAGAAATCTTAGAGCTGATCAAACAGCAACGCCTGAACCGCCTTG 402
        241 TGGAAGGGACCTGCTTTAGGAAACTCAATGCCCGGCGGAGGCAAGACAAGTTTTGGTATT 300
Qγ
           TGGAAGGGACCTGCTTTAGGAAACTCAATGCCCGGCGGAGGCAAGACAAGTTTTGGTATT 462
Db
        301 GTCGGCTTTCGCCAAATCACAAAGTCCTGCATTACGGAGACTTAGAAGAGAGTCCTCAGG 360
Ον
           GTCGGCTTTCGCCAAATCACAAAGTCCTGCATTACGGAGACTTAGAAGAGAGTCCTCAGG 522
Db
        361 GAGAAGTGCCCCACGATTCCTTGCAGGACAAACTGCCGGTGGCAGATATCAAAGCCGTGG 420
Qy
            GAGAAGTGCCCCACGATTCCTTGCAGGACAAACTGCCGGTGGCAGATATCAAAGCCGTGG 582
Dh
        421 TGACGGGAAAGGACTGCCCTCATATGAAAGAGAAAGGTGCCCTTAAACAAAACAAGGAGG 480
            Db
           TGACGGGAAAGGACTGCCCTCATATGAAAGAGAAAGGTGCCCTTAAACAAAACAAGGAGG 642
        481 TGCTTGAACTCGCTTTCTCCATCTTGTATGACTCAAACTGCCAACTGAACTTCATCGCTC 540
            TGCTTGAACTCGCTTTCTCCATCTTGTATGACTCAAACTGCCAACTGAACTTCATCGCTC 702
        541 CTGACAAGCATGAGTACTGTATCTGGACAGATGGACTGAATGCGCTACTCGGGAAGGACA 600
            703 CTGACAAGCATGAGTACTGTATCTGGACAGATGGACTGAATGCGCTACTCGGGAAGGACA 762
        601 TGATGAGCGACCTGACGCGGAATGACCTGGACACCCTGCTCAGCATGGAAATCAAGCTCC 660
Qу
            TGATGAGCGACCTGACGCGGAATGACCTGGACACCCTGCTCAGCATGGAAATCAAGCTCC 822
Db
        661 GCCTCCTGGACCTGGAAAACATCCAGATCCCTGACGCACCTCCGCCGATTCCCAAGGAGC 720
Qγ
            GCCTCCTGGACCTGGAAAACATCCAGATCCCTGACGCACCTCCGCCGATTCCCAAGGAGC 882
        721 CCAGCAACTATGACTTCGTCTATGACTGT 749
Qy
            ADI61697
    ADI61697 standard; cDNA; 2145 BP.
ID
    22-APR-2004
               (first entry)
    Human cDNA downregulated in Alzheimer's disease, INCYTE 405309.8.
    Human; ss; Alzheimer's disease; differential display; neuroprotective;
    brain disorder.
KW
    Homo sapiens.
os
    US6682888-B1.
PN
    27-JAN-2004.
PD
    05-MAY-2000; 2000US-00566921.
PF
    05-MAY-2000; 2000US-00566921.
PR
    (INCY-) INCYTE CORP.
PA
    Loring JF, Tingley DW, Edwards CM; WPI; 2004-118572/12.
PI
DR
    New composition comprising cDNAs that are differentially expressed in
    brain disorders, useful for diagnosing or treating Alzheimer's disease.
PT
    Claim 1; SEQ ID NO 65; 223pp; English.
    The invention relates to a new composition comprising ADI61633-
CC
    ADI61770and their complements that are cDNAs differentially expressed in
    brain disorders. Also included are a high throughput method for detecting
    differential expression of one or more cDNAs in a sample containing
    nucleic acids and a high throughput method for screening a library of
    molecules or compounds to identify a ligand that specifically binds a
    cDNA. The expression of the each of the cDNAs is downregulated at least
    two-fold in the brain of the subjects with Alzheimer's disease (ADI61633-
    ADI61727) or upregulated at least two fold in Alzheimer's disease
    (ADI61728-ADI61770). The composition is useful for diagnosing or treating
    Alzheimer's disease. The present sequence is a cDNA downregulated at
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least two-fold in the brain of the subjects with Alzheimer's disease.
   Sequence 2145 BP; 554 A; 583 C; 474 G; 534 T; 0 U; 0 Other;
                   99.8%; Score 747.4; DB 12; Length 2145;
                   99.9%; Pred. No. 1e-205;
 Best Local Similarity
 Matches 748; Conservative
                        0; Mismatches
        1 GGAGCTTGGTAATGCAGGTGGTGAAGGAGCAGGTTATGAGAGCACTTACAACCAAGCCTA 60
Qy
          198 GGAGCTTGGTAATGCAGGTGGTGAAGGAGCAGGTTATGAGAGCACTTACAACCAAGCCTA 257
Db
        61 GCTCCCTGGACCAGTTCAAGAGCAAACTGCAGAACCTGAGCTACACTGAGATCCTGAAAA 120
Ov
          GCTCCCTGGACCAGTTCAAGAGCAAACTGCAGAAACCTGAGCTACACTGAGATCCTGAAAA 317
Db
       Qν
          318 TCCGCCAGTCCGAGAGATGAACCAGGAAGATTTCCAGTCCCGCCGATTTTGGAACTAA 377
Db
Qy
       181 AGGAGAAGATTCAGCCAGAAATCTTAGAGCTGATCAAACAGCAACGCCTGAACCGCCTTG 240
          Dh
          AGGAGAAGATTCAGCCAGAAATCTTAGAGCTGATCAAACAGCAACGCCTGAACCGCCTTG 437
       {\tt 241} \ {\tt TGGAAGGGACCTGCTTTAGGAAACTCAATGCCCGGCGGAGGCAAGACAAGTTTTGGTATT} \ {\tt 300}
Qy
          Db
       438 TGGAAGGGACCTGCTTTAGGAAACTCAATGCCCGGCGGAGGCAAGACAAGTTTTGGTATT 497
       301 GTCGGCTTTCGCCAAATCACAAAGTCCTGCATTACGGAGACTTAGAAGAGAGTCCTCAGG 360
          GTCGGCTTTCGCCAAATCACAAAGTCCTGCATTACGGAGACTTAGAAGAGAGTCCTCAGG 557
       361 GAGAAGTGCCCCACGATTCCTTGCAGGACAAACTGCCGGTGGCAGATATCAAAGCCGTGG 420
          421 TGACGGGAAAGGACTGCCCTCATATGAAAGAGAAAGGTGCCCTTAAACAAAACAAGGAGG 480
          TGACGGGAAAGGACTGCCCTCATATGAAAGAGAAAGGTGCCCTTAAACAAAACAAGGAGG 677
       481 TGCTTGAACTCGCTTTCTCCATCTTGTATGACTCAAACTGCCAACTGAACTTCATCGCTC 540
          TGCTTGAACTCGCTTTCTCCATCTTGTATGACTCAAACTGCCAACTGAACTTCATCGCTC 737
       541 CTGACAAGCATGAGTACTGTATCTGGACAGATGGACTGAATGCGCTACTCGGGAAGGACA 600
          CTGACAAGCATGAGTACTGTATCTGGACGGATGGACTGAATGCGCTACTCGGGAAGGACA
       601 TGATGAGCGACCTGACGCGGAATGACCTGGACACCCTGCTCAGCATGGAAATCAAGCTCC 660
Qy
          TGATGAGCGACCTGACGCGGAATGACCTGGACACCCTGCTCAGCATGGAAATCAAGCTCC 857
Db
       661 GCCTCCTGGACCTGGAAAACATCCAGATCCCTGACGCACCTCCGCCGATTCCCAAGGAGC 720
Qy
          858 GCCTCCTGGACCTGGAAAACATCCAGATCCCTGACGCACCTCCGCCGATTCCCAAGGAGC 917
       721 CCAGCAACTATGACTTCGTCTATGACTGT 749
Qy
          1111111111111111111111111111111111
       918 CCAGCAACTATGACTTCGTCTATGACTGT 946
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Since the 1st claimed invention has no special technical feature, it cannot share a special technical feature with the other claimed inventions. Thus, Applicant's inventions do not contribute a special technical feature when view over the prior art, they do not have a single inventive concept and so lack unity of invention.

In addition, Group I is directed to a technical feature of a DNA comprising SEQ ID NO:1. Group II is directed to a technical feature of a DNA comprising SEQ ID NO:2. Group III is directed to a technical feature of a DNA comprising SEQ ID NO:3. Group IV is directed to a technical feature of a peptide comprising SEQ ID NO:4. Group V is directed to a technical feature of a peptide comprising SEQ ID NO:5. Group VI is directed to a technical feature of a peptide comprising SEQ ID NO:6. Group VII is directed to a technical feature of an antibody against SEQ ID NO:4. Group VIII is directed to a technical feature of a method for detecting nerve stem/progenitor cells. using SEQ ID NO:1. Group IX is directed to a technical feature of a method for a drug for nerve differentiation factor or inhibitor of nerve differentiation. Group X is directed to a technical feature of an antibody against SEQ ID NO:5. Group XI is directed to a technical feature of an antibody against SEQ ID NO:6. Group XII is directed to a technical feature of a method for detecting nerve stem/progenitor cells using SEQ ID NO:2. Group XIII is directed to a technical feature of a method for detecting nerve stem/progenitor cells using SEQ ID NO:3. Group XIV is directed to a technical feature of a method for detecting nerve stem/progenitor cells using SEQ ID NO:4. Group XV is directed to a technical feature of a method for detecting nerve stem/progenitor cells using SEQ ID NO:5. Group XVI is directed to a technical feature of a method for detecting nerve stem/progenitor cells using SEQ ID NO:6. Group XVII is directed to a technical feature of a method for detecting nerve stem/progenitor cells using an antibody against SEQ ID NO:4. Group XVIII is directed to a technical feature of a method for detecting nerve stem/progenitor cells using an antibody against SEQ ID

NO:5. Group XIX is directed to a technical feature of a method for detecting nerve stem/progenitor cells using an antibody against SEQ ID NO:6.

Therefore, the above Inventions do not share a common special technical feature as they comprise different steps and utilize different products, which demonstrates that each method has a different mode of operation. In addition, each invention uses structurally and functionally divergent materials. A method for detecting nerve stem/progenitor cells does not have a same corresponding technical feature as that in a method of screening for a drug. Accordingly, Groups I-XIX are not so linked by the same or a corresponding special technical feature within meaning of PCT Rule 13.1 so as to form a single general inventive concept.

- 4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated Groups I-XIX as set forth above to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups.
- 5. The examiner has required restriction between product and process claims.

 Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

<u>All</u> claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday and every other Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (571) 272-0841.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/ Chang-Yu Wang, Ph.D. September 27, 2007

> CHRISTINE J. SAOUD PRIMARY EXAMINER

Chustin D. Saoud